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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/070,328	04/08/2004	Roberto Takashi Sudo	32390-178943	9691

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EXAMINER

RAO, DEEPAK R

ART UNIT	PAPER NUMBER
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1624

DATE MAILED: 06/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/070,328	SUDO ET AL.	
	Examiner	Art Unit	
	Deepak Rao	1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 March 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11, 16-20 and 22-27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-11, 16-19 and 22-27 are allowed.
- 6) ☒ Claim(s) 20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This office action is in response to the amendment filed on March 20, 2006.

Claims 1-11, 16-20 and 22-27 are pending in this application.

Withdrawn Rejections/Objections:

Applicant is notified that any outstanding rejection/objection that is not expressly maintained in this office action has been withdrawn or rendered moot in view of applicant's amendments and/or remarks.

The following rejections are maintained:

Claim 20 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a composition comprising the compound of claim 5 and a pharmaceutically acceptable carrier, does not reasonably provide enablement for a composition having the characteristic of producing at least 20% oral bioavailability of the compound. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. The reasons provided in the previous office action are incorporated here by reference.

Applicant's arguments have been fully considered but they were not deemed to be persuasive. Applicant argues that 'there is no undue experimentation because known di- or tripeptides are included with the compound of claim 5 in the composition'. The instant claim 20 is drawn to "a chemical composition comprising the compound of claim 5 and a second peptide compound; said composition having the characteristic of producing at least 20% bioavailability

Art Unit: 1624

of the compound when taken orally”, for which there is insufficient enablement in the specification regarding the types of composition intended by the claim. In general compounds ‘that increase the bioavailability of a compounds’ are known as prodrugs. Applicant indicates that ‘the scope of the invention includes creating a prodrug of LASSBio294 compound by combining with a carrier molecule to increase the bioavailability’, however, there is no description of any such prodrugs of the compound or a method of preparation of the same. The specification does not provide any explanation regarding how the instantly recited characteristic for the composition to ‘produce 20% oral bioavailability’ is established. There is neither a procedure describing how such compositions are prepared nor examples that illustrate the recited activity. Further, the instant claims appear to be ‘reach through’ claims. Reach through claims, in general have a format drawn to a characteristic or functionality of the compound or composition and thereby reach through to all types of compositions, for which they lack written description and enabling disclosure in the specification thereby requiring undue experimentation for one of skill in the art to practice the invention.

Oral bioavailability is an important parameter in the development of drug candidates. While there are various *in-vitro* assays that have been developed to enable rapid and efficient screening for the effects which profoundly alter bioavailability of a drug, such tests and data require thorough interpretation of the results from *in-vitro* experiments in order to forecast oral pharmacokinetics of a compound. Transporters play an important role in enhancing the oral bioavailability and applicant recites the broad class of dipeptide and tripeptides as the carrier molecules to be combined with the compound to increase the oral bioavailability of the drug in oral formulation. Applicant has neither described nor provided working examples for the

Art Unit: 1624

combination of the invention compound with various types of dipeptides or tripeptides as the 'second peptide compound' intended by the instant claim language. These types of combinations do not depend on the novelty of the claimed compounds for patentability, but instead require separate inventive effort. The disclosure therefore cannot rely on the state of the art in providing the necessary description of the types of 'chemical compositions' intended by the instant claims. None of the types of 'chemical compositions' recited in the claims were prepared by applicants or specifically suggested in the disclosure. The relevant search in the state of the art did not reveal any such compositions having the instantly recited characteristic or activity and therefore, one of ordinary skill in the art would have the burden of undue experimentation to prepare the claimed compositions.

Allowable Subject Matter

Claims 1-11, 16-19 and 22-27 are allowed. The references of record do not teach or fairly suggest the instantly claimed compounds.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

Art Unit: 1624

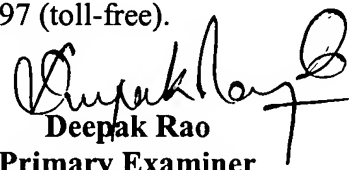
will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deepak Rao whose telephone number is (571) 272-0672. The examiner can normally be reached on Tuesday-Friday from 6:30am to 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson, can be reached at (571) 272-0661. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Deepak Rao
Primary Examiner
Art Unit 1624

June 1, 2006